



PATENT
Customer No. 22,428
Attorney Docket No. 080618-0237

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: John P. Cooke et al.
Title: Enhancement of Vascular Function by Modulation of
Endogenous Nitric Oxide Production or Activity
Appln. No.: 10/618,835
Filing Date: 07/15/2003
Examiner: J. Russel
Art Unit: 1654

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted are the following items:

Information Disclosure Statement Under 37 C.F.R. § 1.97 (b) (10 pages);

Form PTO/SB/08 (13 pages);

D. PEARSON and S. SHAW, The Life Extension Companion, Warner Books (1984), NY, pp. cover to
cover (1325 pages total);

Pleadings noted in IDS and cited items therein, as listed in below:

- A. Complaint for Patent Infringement and Demand for Jury Trial (5 pgs.), including:
 - Exhibit A – (12 pgs.)
 - Exhibit B - (27 pgs.);
- B. Answer of Defendant Real Health Laboratories, Inc. to Complaint for Patent Infringement;
and Counterclaim for Declaratory Judgment of Invalidity (11 pgs.);
- C. Plaintiff's Answer to Defendant Real Health Laboratories, Inc.'s Counterclaim for
Declaratory Judgment of Invalidity (4 pgs.);
- D. Second Complaint 02CV 0129 H (John Dullea as an Individual) (12 pgs.), including:
 - Exhibit A (11 pgs.)
 - Exhibit B (14 pgs.)

Exhibit C (4 pgs.)

- E. Plaintiff's Rule 26(a)(1) Initial Disclosures (93 pgs);
- F. Plaintiff's Answers to Defendant's First Set of Interrogatories (12 pgs.), including:

Exhibit A (1 pg.)

Exhibit B (4 pgs.);

- G. Plaintiff's Responses to Defendant's First Set of Requests for Production of Documents and Things (27 pgs.);
- H. Defendant Real Health Laboratories, Inc.'s Supplemental and Amended Objections and Responses to Plaintiffs Cooke Pharma, Inc. and the Board of Trustees of Leland Stanford Junior University's First set of Requests for Production of Documents and Things (26 pgs.);
- I. Defendant-Counterdefendant Real Health Laboratories, Inc.'s Objections and Responses to Plaintiffs Cooke Pharma, Inc. and the Board of Trustees of Leland Stanford Junior University's First Set of Interrogatories (13 pgs.);
- J. Defendant-Counterclaimant Real Health Laboratories, Inc.'s Supplemental and Amended Objections and Responses to Plaintiffs-Counterdefendants Cooke Pharma, Inc. and the Board of Trustees of Leland Stanford Junior University's First set of Requests for Admission (Nos. 1-39) (14 pgs.)
- K. Defendant-Counterclaimant Real Health Laboratories, Inc.'s Objections and Responses to Plaintiffs-Counterdefendants Cooke Pharma, Inc. and the Board of Trustees of Leland Stanford Junior University's Second Set of Requests for Admission (Nos. 40-75) (14 pgs.);
- L. Defendant-Counterclaimant Real Health Laboratories, Inc.'s Supplemental and Amended Objections and Responses to Plaintiffs Cooke Pharma, Inc. and the Board of Trustees of Leland Stanford Junior University's First Set of Requests for Production of Documents and Things (Nos. 1-53) (26 pgs.);
- M. Defendant-Counterclaimant Real Health Laboratories, Inc.'s Objections and Responses to Plaintiffs-Counterdefendants Cooke Pharma, Inc. and the Board of Trustees of Leland Stanford Junior University's 2nd Set of Requests for Production of Documents and Things (Nos. 54-56) (8 pgs.);
- N. Defendant-Counterclaimant Real Health Laboratories, Inc.'s Supplemental and Amended Objections and Responses to Plaintiffs Cooke Pharma, Inc. and the Board of Trustees of Leland Stanford Junior University's First Set of Interrogatories (Nos. 1-11) (13 pgs.);
- O. Defendant-Counterclaimant Real Health Laboratories, Inc.'s Objections and Responses to Plaintiffs-Counterdefendants Cooke Pharma, Inc. and the Board of Trustees of Leland Stanford Junior University's 2nd Set of Interrogatories (Nos. 12-17, including subparts) (9 pgs.);

- **P.** Defendant-Counterclaimant Real Health Laboratories Lab., Expert Witness Report of Distinguished Professor Alfred Stracher (14 pgs.), including:
 - Exhibit A (8 pgs.)
 - Exhibit B (4 pgs.)
 - Exhibit C (17 pgs.)
 - Exhibit D (5 pgs.);
- **Q.** Defendant-Counterclaimant Real Health Lab. Supplemental and Amended Response to Plaintiffs-Counterdefendants Cooke Pharma, and the Board of Trustees of Leland Stanford Junior University's 2nd Set of Requests for Admission No. 66 (3 pgs.);
- **R.** Defendant-Counterclaimant Real Health Lab. 2nd Supplemental and 2nd Amended Objections and Responses to Plaintiffs Cooke Pharma, and the Board of Trustees of Leland Stanford Junior and 2nd Sets of Interrogatories (Nos. 1-7, 9, 10 and 12-14) (17 pages);
- **S.** Plaintiffs' Third Set of Request for Admission to Defendant Real Health Laboratories, Inc. (4 pgs.);

Tab No.	Document
	Date stamped postcard from application no. 10/060,252, dated 07/10/2003 (1 page);
1	ANB's Joinder in Daily Wellness' Motion for Summary Judgment of Invalidity of the Claims at Issue Under the Doctrine of Inherency (3 pages)
2	Appendix 1 – U.S. Patent 5,217,997, Claim 12 (2 pages)
3	Appendix 1 – U.S. Patent 5,217,997, Claims 9 and 11; Appendix 2 – U.S. Patent 5,428,070, Claims 1 and 3; Appendix 3 – U.S. Patent 5,891,459, Claims 17 and 20; and Appendix 4 – U.S. Patent 6,117,872, Claims 4 and 5 (10 pages)
4	Exhibit K – Palmer et al., "L-Arginine is the Physiological Precursor for the Formation of Nitric Oxide in Endothelium-Dependent Relaxation," <u>Biochem. Biophys. Res. Comm.</u> 153:1251-56 June 1988 (7 pages)
5	Exhibit J – Part 3 – Patent preliminary infringement contentions against defendant Advanced Nutritional Biosystems (15 pages)
6	Exhibit J – Part 2 – Patent preliminary infringement contentions against defendant Daily Wellness (16 pages)
7	Exhibit J – Part 1 – Plaintiff's Disclosure of Asserted Claims and Preliminary Infringement Contentions (10 pages)
8	Exhibit I – The Nobel Prize in Physiology or Medicine 1998, presentation speech (2003) (4 pages)

Tab No.	Document
9	Exhibit H – PDR on-line bookstore “L-Arginine” trade names (8 pages)
10	Exhibit G – The Columbia Encyclopedia, “amino acid” (2001) (2 pages)
11	Exhibit F – U.S. Patent 6,117,872 (15 pages)
12	Exhibit E – U.S. Patent 5,891,459 (27 pages), and Certificate of Correction (1 page);
13	Exhibit D – U.S. Patent 5,428,070 (12 pages)
14	Exhibit C – U.S. Patent 5,217,997 (12 pages)
15	Exhibit B – (manually filed see docket #35)(2 pages)
16	Exhibit A – The Columbia Encyclopedia “arginine” (2 pages)
17	Notice of Motion and Motion for Summary Judgment of Invalidity of the Claims at Issue under the Doctrine of Inherency (19 pages)
18	Declaration of Anup Tikku in Support of Daily Wellness’ Motion for Summary Judgment of Invalidity of the Claims at Issue under the Doctrine of Inherency (3 pages)
19	[Proposed] Order Granting Daily Wellness’ Motion for Summary Judgment of Invalidity (2 pages); and
20	Plaintiff’s List of Proposed Terms and Claim Elements for Construction Pursuant to Patent Local Rule 4-1 (5 pages)

- NAKAKI et al.; “Beneficial Circulatory Effect of L-Arginine”; *Jpn J Pharmacol.*, Vol. 66, (05-23-94), pp. 167-71.
- ITO, THOMAS Y., et al., “A Double-Blind Placebo-Controlled Study of ArginMax, a Nutritional Supplement for Enhancement of Female Sexual Function,” *Journal of Sex & Marital Therapy*, vol. 27, no. 5, October-December, 2001, pp. 541-549.
- SCHACHTER, ALEXANDER, M.D., et al., “Treatment of Oligospermia with the Amino Acid Arginine,” *International Journal of Gynaecology and Obstetrics*, vol. 11, no. 5, 1973, pp. 206-209.
- Derwent Abstract of JP 50048189 A, 04/30/1975, “Fermentative production of L-arginine – in presence of antibiotics, surfactants and antioxidants,” 1 page.
- Derwent Abstract of JP 57005692 A, 01/12/1982, “Fermentative production of L-arginine – by incubation of microorganism of genus *Brevibacterium* or *Corynebacterium*,” 1 page.
- Derwent Abstract of JP 57093913 A, 06/11/1982, “Potentiator for action of spermatozoa – comprises arginine and vitamin-E,” 1 page.

- Derwent Abstract of JP 58055418 A, 04/01/1983, "Hyperlipaemic treatment composition – containing monocolin K and ML-236B carbonate, formed with basic macromolecular compounds, e.g. ion-exchanging polypeptide(s)," 1 page.
- Derwent Abstract of EP 441119 A, 08/14/1991, "Use of L-arginine – to treat high vascular resistance disorders, e.g. hypertension and bronchial asthma," 2 pages.
- Derwent Abstract of EP 511587 A, 11/04/1992, "Slimming beverage- comprises an aminoacid capable of accelerating release of glucagon, a xanthine derivative and thiamine compound in appropriate vehicle," 2 pages.
- Derwent Abstract of EP 511118 A, 10/28/1992, "Use of lysine and arginine pyrrolidone carboxylate(s) as anti-oxidants – preferably with a phenolic derivative, e.g. tocopherol, in pharmaceutical and cosmetic compositions, particularly to protect skin from ageing," 2 pages.
- Derwent Abstract of EP 546796 A, 06/16/1993, "Use of L-arginine – for treating and preventing atherosclerosis," 1 page.
- Inpadoc Abstract of ZA 9410015 A, 11/08/1995, "A pharmaceutical composition," 1 page.
- Derwent Abstract of WO 9318156 A, 09/16/1993, "Endothelial nitric oxide synthase and gene – which catalyses nitric oxide formation, for, e.g., inhibiting platelet aggregation or smooth muscle cell proliferation," 1 page.
- Derwent Abstract of JP 7163269A, 06/27/1995, "Bearing cattle of special gender – by controlling amount of arginine and calcium in feedstuff," 1 page.
- Derwent Abstract of FR 2547501 A, 12/21/1984, "Arginine carbonate, citric acid compositions – giving effervescent agents for tablets, free from alkaline earth metals," 1 page.
- 5,229,390--MORIYAMA et al.-07-20-1993
- 5,352,695--N'GUYEN et al.-10-04-1994

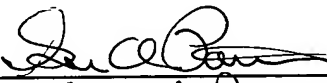
The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date 04-19-2004

FOLEY & LARDNER LLP
Customer Number: 22428

Telephone: (202) 672-5569
Facsimile: (202) 672-5399

By  (45,943)
SEAN A. PASSINO
Stephen B. Maebius
Attorney for Applicants
Registration No. 35,264
For

Should additional fees be necessary in connection with the filing of this paper, or if a petition for extension of time is required for timely acceptance of same, the Commissioner is hereby authorized to charge Deposit Account No. 19-0741 for any such fees; and applicant(s) hereby petition for any needed extension of time.



PATENT
Customer No. 22,428
Attorney Docket No. 080618-0237

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: John P. Cooke et al.
Title: Enhancement of Vascular Function by Modulation of
Endogenous Nitric Oxide Production or Activity
Appln. No.: 10/618,835
Filing Date: 07/15/2003
Examiner: J. Russel
Art Unit: 1654

INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. § 1.97(b)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicants bring to the Examiner's attention the documents on the attached form PTO/SB/08 and pleadings from a litigation concerning parent patents of the present application. This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits for the above-referenced application.

This application is a continuation of U.S. Application No. 10/060,252, filed February 1, 2002, now U.S. Pat. No. 6,646,006, which application is a continuation of U.S. Application 09/930,833, filed August 15, 2001, now abandoned, which application is a continuation of U.S. Application No. 09/075,509, filed May 8, 1998, now U.S. Pat. No. 6,337,321, which application is a continuation of 08/556,035, filed November 9, 1995, now U.S. Pat. No. 5,891,459, which application is a continuation-in-part of U.S. Application No. 08/336,159, filed November 8, 1994, now abandoned,

which application is a continuation-in-part of 08/076,312, filed June 11, 1993, now U.S. Pat. No. 5,428,070.

A. Documents

Copies of the listed documents A1-A229 were previously submitted in prior application no. 10/060,252, filed February 1, 2002, now U.S. Pat. No. 6,646,006, and/or its parents, grandparents, etc., upon which applications Applicants rely for the benefits of 35 U.S.C. §§ 120 and 121.

Copies of documents A204, A224-A225, and A228 are resubmitted.

Copies of documents A230-A241 and B1-B2 are attached.

Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

a. Non-English language documents

JP 50-48189 (04/30/1975) (A48): Attached with this filing is a Derwent Abstract of this document (A230).

JP 57-5692 (01/12/1982) (A49): Attached with this filing is a Derwent Abstract of this document (A231).

JP 57-93913 (06/11/1982) (A50): Attached with this filing is a Derwent Abstract of this document (A232).

JP 58-55418 (04/01/1983) (A51): Attached with this filing is a Derwent Abstract of this document (A233).

JP 3-21786 (01/30/1991) (A53): This document was indicated as considered by the Examiner in the SB/08 of the '252 application.

EP 0511118A1 (L'Oreal) (04/24/1992) (A55): Attached with this filing is a Derwent Abstract of this document (A236). According to the abstract, U.S. Pat. No. 5,352,695 (B2) is in the same family.

JP 7-163269 (06/27/1995) (A59): Attached with this filing is a Derwent Abstract of this document (A240).

FR 2,547,501 (Donzeau) (12/21/1984) (A60): Attached with this filing is a Derwent Abstract of this document (A241).

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and Applicants determine that the cited documents are not "prior art" under United States law, then Applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

B. Litigations

1. Real Health Litigations

The current application is in a family whose patents are involved in litigation. As reported in the an earlier-filed application, both the '459 and the '070 patents were involved in a patent infringement suit in the United States District Court for the Southern District of California (Case No. 01 CV 0854 W). The assignee and exclusive licensee of the '070 and '459 patents, Stanford University and Cooke Pharma, Inc,

respectively, filed a complaint for patent infringement against defendant Real Health Laboratories, Inc. (Real Health) on May 17, 2001. Among other things, Real Health asserted that the '459 and the '070 claims at issue in the civil suit were invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112. The patent infringement suit involving the '459 and the '070 patents was settled before trial, with no decision on the validity of either patent being argued or rendered.

Listed on the accompanying SB/08 forms are references, some of which were produced to counsel for the patentee and used by the defendant in the above-mentioned civil case in its assertion that the claims at issue were invalid.

Also, enclosed and listed herein and in the record of the parent application are copies of pleadings and discovery requests generated in the above-mentioned civil suit which the Office may or may not consider material to patentability of the current application. Once again, the submission of the court-related documents herewith is not intended as an admission that such documents or arguments contained therein are material to patentability.

- A. Complaint for Patent Infringement and Demand for Jury Trial;
- B. Answer of Defendant Real Health Laboratories, Inc. to Complaint for Patent Infringement; and Counterclaim for Declaratory Judgment of Invalidity;
- C. Plaintiff's Answer to Defendant Real Health Laboratories, Inc.'s Counterclaim for Declaratory Judgment of Invalidity;
- D. Second Complaint 02CV 0129 H (John Dullea as an Individual);
- E. Plaintiff's Rule 26(a)(1) Initial Disclosures;
- F. Plaintiff's Answers to Defendant's First Set of Interrogatories;

- G. Plaintiff's Responses to Defendant's First Set of Requests for Production of Documents and Things;
- H. Defendant Real Health Laboratories, Inc.'s Supplemental and Amended Objections and Responses to Plaintiffs Cooke Pharma, Inc. and the Board of Trustees of Leland Stanford Junior University's First Set of Requests for Production of Documents and Things;
- I. Defendant-Counterdefendant Real Health Laboratories, Inc.'s Objections and Responses to Plaintiffs Cooke Pharma, Inc. and the Board of Trustees of Leland Stanford Junior University's First Set of Interrogatories;
- J. Defendant-Counterclaimant Real Health Laboratories, Inc.'s Supplemental and Amended Objections and Responses to Plaintiffs-Counterdefendants Cooke Pharma, Inc. and the Board of Trustees of Leland Stanford Junior University's First set of Requests for Admission (Nos. 1-39);
- K. Defendant-Counterclaimant Real Health Laboratories, Inc.'s Objections and Responses to Plaintiffs-Counterdefendants Cooke Pharma, Inc. and the Board of Trustees of Leland Stanford Junior University's Second Set of Requests for Admission (Nos. 40-75);
- L. Defendant Real Health Laboratories, Inc.'s Supplemental and Amended Objections and Responses to Plaintiffs Cooke Pharma, Inc. and the Board of Trustees of Leland Stanford Junior University's First Set of Requests for Production of Documents and Things (Nos. 1-53);
- M. Defendant-Counterclaimant Real Health Laboratories, Inc.'s Objections and Responses to Plaintiffs-Counterdefendants Cooke Pharma, Inc. and the Board of

Trustees of Leland Stanford Junior University's 2nd Set of Requests for Production of Documents and Things (Nos. 54-56);

N. Defendant-Counterclaimant Real Health Laboratories, Inc.'s Supplemental and Amended Objections and Responses to Plaintiffs Cooke Pharma, Inc. and the Board of Trustees of Leland Stanford Junior University's First Set of Interrogatories (Nos. 1-11);

O. Defendant-Counterclaimant Real Health Laboratories, Inc.'s Objections and Responses to Plaintiffs-Counterdefendants Cooke Pharma, Inc. and the Board of Trustees of Leland Stanford Junior University's 2nd Set of Interrogatories (Nos. 12-17, including subparts);

P. Defendant-Counterclaimant Real Health Laboratories, Inc.'s, Expert Witness Report of Distinguished Professor Alfred Stracher;

Q. Defendant-Counterclaimant Real Health Laboratories, Inc.'s, Supplemental and Amended Response to Plaintiffs-Counterdefendants Cooke Pharma, and the Board of Trustees of Leland Stanford Junior University's 2nd Set of Requests for Admission No. 66;

R. Defendant-Counterclaimant Real Health Laboratories, Inc.'s, 2nd Supplemental and 2nd Amended Objections and Responses to Plaintiffs Cooke Pharma, and the Board of Trustees of Leland Stanford Junior and 2nd Sets of Interrogatories (Nos. 1-7, 9, 10 and 12-14); and

S. Plaintiff's Third Set of Requests for Admission to Defendant Real Health Laboratories, Inc.

Other pleadings were filed in the file history of the parent case (the '252 application) but are not resubmitted here. These include:

- Real Health's Notice of Motion and Motion to Bifurcate Liability Issues from Damages and to Stay All Proceedings as to Damages; Memorandum in Support of Points and Authorities in Support;
- Memorandum of Points and Authorities in Opposition to Defendant Real Health Laboratories, Inc.'s Motion to Bifurcate Issues from Damages and to Stay all Proceedings as to Damages;
- Declaration of Kenneth S. Klein in Support of Opposition to Defendant Real Health Laboratories, Inc.'s Motion to Bifurcate Issues from Damages and to Stay all Proceedings as to Damages;
- Plaintiff's Notice of Lodgment of Authority taken from an Electronic Database;
- Real Health's Reply in Further Support of its Motion to Bifurcate Liability Issues from Damages and to stay all Proceedings as to Damages, Declaration of Client;
- Order Denying Defendant's Motion to Bifurcate Liability Issues from Damages and to stay all Damages Proceedings;
- Subpoena: Dr. Robert Fried, Ph.D.; and
- Real Health's Notice of Written Disclosure of Expert Witnesses.

Applicants will submit a docket sheet and any document to the Examiner, if the Examiner makes such a request.

2. Daily Wellness and Advanced Nutritional Biosystems Litigations

Also submitted are copies of the Motion for Summary Judgment and related papers filed in a second ongoing litigation against other defendants Daily Wellness and Advanced Nutritional Biosystems (CV 02-05284 in N. Dist. of Cal. San Jose division is representative of the suits). The as-filed papers are listed as follows:

1. ANB's Joinder in Daily Wellness' Motion for Summary Judgment of Invalidity of the Claims at Issue Under the Doctrine of Inherency;
2. Appendix 1 – U.S. Patent 5,217,997, Claim 12;
3. Appendix 1 – U.S. Patent 5,217,997, Claims 9 and 11; Appendix 2 – U.S. Patent 5,428,070, Claims 1 and 3; Appendix 3 – U.S. Patent 5,891,459, Claims 17 and 20; and Appendix 4 – U.S. Patent 6,117,872, Claims 4 and 5;
4. Exhibit K – Palmer et al., "L-Arginine is the Physiological Precursor for the Formation of Nitric Oxide in Endothelium-Dependent Relaxation," Biochem. Biophys. Res. Comm. 153:1251-56 June 1988;
5. Exhibit J – Part 3 – Patent preliminary infringement contentions against defendant Advanced Nutritional Biosystems;
6. Exhibit J – Part 2 – Patent preliminary infringement contentions against defendant Daily Wellness;
7. Exhibit J – Part 1 – Plaintiff's Disclosure of Asserted Claims and Preliminary Infringement Contentions;
8. Exhibit I – The Nobel Prize in Physiology or Medicine 1998, presentation speech (2003);
9. Exhibit H – PDR on-line bookstore "L-Arginine" trade names;
10. Exhibit G – The Columbia Encyclopedia, "amino acid" (2001);
11. Exhibit F – U.S. Patent 6,117,872;
12. Exhibit E – U.S. Patent 5,891,459;
13. Exhibit D – U.S. Patent 5,428,070;
14. Exhibit C – U.S. Patent 5,217,997;
15. Exhibit B – (manually filed, see docket #35);

16. Exhibit A – The Columbia Encyclopedia entry for "arginine;"
17. Notice of Motion and Motion for Summary Judgment of Invalidity of the Claims at Issue under the Doctrine of Inherency;
18. Declaration of Anup Tikku in Support of Daily Wellness' Motion for Summary Judgment of Invalidity of the Claims at Issue under the Doctrine of Inherency; and
19. [Proposed] Order Granting Daily Wellness' Motion for Summary Judgment of Invalidity.

Each item 1-19 was submitted in the '252 application 07-10-2003 and is submitted here again.

The following item is presented for the first time:

20. Plaintiff's List of Proposed Terms and Claim Elements for Construction Pursuant to Patent Local Rule 4-1.

The Examiner is requested to indicate on the record that he considered each item.

a. Motions For Summary Judgment of Patent Invalidity

The Examiner's attention is directed to Items 1 and 17, which contain arguments of unpatentability from each defendant. For example, item 17 at pages 5-6 discusses the "*Life Extension* book," i.e., document A228. According to item 17, the "*Life Extension* book" discloses the compositions that render the patented claims invalid. *Life Extension, supra.* at pp. 461-62; 467-68; 485; 611-13; 620 (see A229). Defendant argued that these compositions formed the basis to invalidate claims of patents in the present application's family. Item 17 at 6-end.

The second defendant, ANB, made arguments in Item 1 and joined with the first defendant's position in Item 17.

The request for attention should not be construed as a representation that any other part of this submission is any less relevant. The Examiner is respectfully requested to consider each submission in its entirety.

Applicants will submit a docket sheet and any document to the Examiner, if the Examiner makes such a request.

CONCLUSION

The Examiner is invited to contact Sean A. Passino (45,943) at (202) 295-4166 if any questions may be resolved by a telephone conference.


The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date 04-19-2004

FOLEY & LARDNER LLP
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By  (45,943)
SEAN A. PASSINO FOR
Stephen B. Maebius
Attorney for Applicants
Registration No. 35,264

Should additional fees be necessary in connection with the filing of this paper, or if a petition for extension of time is required for timely acceptance of same, the Commissioner is hereby authorized to charge Deposit Account No. 19-0741 for any such fees; and applicant(s) hereby petition for any needed extension of time.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

Date Submitted: April 19, 2004

(use as many sheets as necessary)

Complete if Known

Application Number	10/618,835
Filing Date	07/15/2003
First Named Inventor	John P. Cooke
Group Art Unit	1654
Examiner Name	J. Russel
Attorney Docket Number	080618-0237

Sheet 1 of 13

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
	A1	2,878,124		KRULKENBERG	03-17-1959	
	A2	3,015,567		HAUSE et al.	01-02-1962	
	A3	3,360,374		BARR, SR. et al.	12-26-1967	
	A4	3,970,750		BROCKEMEYER et al.	07-20-1976	
	A5	4,168,307		OKAMOTO et al.	09-18-1979	
	A6	4,340,592		ADIBI	07-20-1982	
	A7	4,900,566		HOWARD	02-13-1990	
	A8	4,920,098		COTTER et al.	04-24-1990	
	A9	4,957,938		ANDERSON et al.	09-18-1990	
	A10	5,032,377		RADEMACHERS et al.	07-16-1991	
	A11	5,032,608		DUDRICK	07-16-1991	
	A12	5,034,377		ADIBI et al.	07-23-1991	
	A13	5,036,052		OZEKI et al.	07-30-1991	
	A14	5,041,429		SAWAI et al.	08-20-1991	
	A15	5,106,836		CLEMENS et al.	04-21-1992	
	A16	5,157,022		BARBUL	10-20-1992	
	A17	5,171,217		MARCH et al.	12-15-1992	
	A18	5,217,997		LEVERE et al.	06-08-1993	
	A19	5,221,668		HENNINGFIELD et al.	06-22-1993	
	A20	5,248,688		DUDRICK	09-28-1993	
	A21	5,262,435		JOSHUA et al.	11-16-1993	
	A22	5,278,189		RATH et al.	01-11-1994	
	A23	5,288,490		BUDZYNSKI et al.	02-22-1994	
	A24	5,296,246		INOUE et al.	03-22-1994	
	A25	5,326,569		ACOSTA et al.	07-05-1994	
	A26	5,334,617		ULRICH et al.	08-02-1994	
	A27	5,364,644		WALASZEK et al.	11-15-1994	
	A28	5,374,651		KILBOURN et al.	12-20-1994	
	A29	5,380,945		MURAD et al.	01-10-1995	
	A30	5,385,940		MOSKOWITZ	01-31-1995	
	A31	5,428,070		COOKE et al.	06-27-1995	
	A32	5,464,644		WULLSCHLEGER et al.	11-07-1995	
	A33	5,543,430		KAESEMEYER et al.	08-06-1996	
	A34	5,576,287		ZALOGA et al.	11-19-1996	
	A35	5,576,351		YOSHIMURA et al.	11-19-1996	
	A36	5,626,883		PAUL	05-06-1997	
	A37	5,631,031		MEADE	05-20-1997	
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				Filing Date	07/15/2003
				First Named Inventor	John P. Cooke
				Group Art Unit	1654
				Examiner Name	J. Russel
				Attorney Docket Number	080618-0237
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				Group Art Unit	1654
				Examiner Name	J. Russel
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	A213	KEYSARY et al.; "The involvement of L-Arginine-Nitric Oxide Pathway in the Anti-Rickettsial Activity of Macrophagelike cells"; <i>Biochemical, Pharmacological, and clinical aspects of Nitric Oxide</i> (1995), pp. 111-14.	
	A214	STARKE; "Streptozotocin chemotherapy in patients with malignant metastatic insulinomas"; <i>Experimental and Clinical Endocrinology & Diabetes</i> , Vol. 103 (2) (1995) (Abstract), p. A53.	
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	A221	HISHIKAWA, KEIICHI, M.D., et al., "Effect of Systemic L-Arginine Administration on Hemodynamics and Nitric Oxide Release in Man," <i>Japanese Heart Journal</i> , vol. 33, no. 1, January 1992, pp. 41-48.	
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	A226	POLAN, MARY LAKE, M.D. et al., "Clinical Study of ArginMax, a Nutritional Supplement for the Enhancement of Female Sexual Function," <i>Journal of Women's Health & Gender-Based Medicine</i> , vol. 10, no. 4, May 2001, p. 401.	
	A227	HANSEN, JANICE I., M.D., et al., "Clinical Study of ArginMax, a Nutritional Supplement for the Enhancement of Female Sexual Function," <i>Journal of Women's Health & Gender-Based Medicine</i> , vol. 11, no. 3, April 2002. (one page).	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: April 19, 2004 <i>(use as many sheets as necessary)</i>				Application Number	10/618,835
				Filing Date	07/15/2003
				First Named Inventor	John P. Cooke
				Group Art Unit	1654
				Examiner Name	J. Russel
Sheet	13	of	13	Attorney Docket Number	080618-0237

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	A228	D. PEARSON and S. SHAW, <u>The Life Extension Companion</u> , Warner Books (1984), NY, pp. cover to cover (1325 pages total).	
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	A230	Derwent Abstract of JP 50048189 A, 04/30/1975, "Fermentative production of L-arginine – in presence of antibiotics, surfactants and antioxidants," 1 page.	
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